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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/200,791	11/30/1998	THOMAS M. BEHR	018734/0161	9799
26633	7590	09/29/2005		
HELLER EHRMAN WHITE & MCAULIFFE LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001				
			EXAMINER FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/200,791

Applicant(s)

BEHR ET AL.

Examiner

Brandon J. Fetterolf, PhD

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 07 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 09/07/2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-9, 11-21, 23-29 and 31-41.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached document.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

*KU*

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Behr et al.

The examiner of the application has changed. This case has now been transferred as of 07/09/2005. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Brandon Fetterolf, Group Art Unit 1642.

### ***Application Status***

The Amendment filed on 09/07/2005 in response to the previous Final Office Action (06/07/2005) is acknowledged and has been entered.

Claims 1-9, 11-21, 23-29 and 31-41 are currently pending and under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

### **Priority:**

The instant application is a CIP of 08/407,8999 filed 3/21/1995 (now U.S. Patent 5,843,894) and claims the limitation of a method of reducing kidney retention of a protein conjugate. A careful review of the prior application does not appear to recite this limitation and as such, has been given the priority date of 11/30/1998 as set forth in the previous office action.

In reference to the prior Office Action (06/07/2005, pages 3-4) which held that the instant claims, reciting a method of reducing kidney retention of a protein conjugate, are not entitled to the benefit of the filing date of USSN 08/407,899, March 21, 1995 (now US Patent 5,843,894), for the asserted reason that the species "antibodies" disclosed in USSN 08/407,899 does not support the genus of "protein conjugate," of the claims, Applicant's assert that the disclosure of antibodies in the parent case would have shown the skilled artisan at the time of the invention that applicants were in possession of the invention citing *Vas-Cath Inc. v. Mahurkar* 935 F. 2d 1555, 19 USPQ 2d 1111 (Fed. Cir. 1991) and incorporate all previous arguments made in connection with this issue.

These arguments have been carefully considered but are not found persuasive.

The instant application was given a priority date of 11/30/1998 because the '894 patent, directed to reducing renal uptake of an antibody and antibody fragment conjugates, does not appear

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to contemplate or suggest a method of reducing renal uptake of the presently claimed genus of protein conjugates. In reference to *Vas-Cath Inc. v. Mahurkar*, it appears that the fact patterns involved in the instant application are different from those concerned in *Vas-Cath Inc. v. Mahurkar*. In *Vas-Cath Inc. v. Mahurkar*, the question decided by the courts was whether the drawings recited in the prior application conveyed with reasonable clarity to those of ordinary skill that Mahurkar had in fact invented the catheter recited in the those claims, having (among several other limitation) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens. In the instant application, the question is not whether the drawings (i.e. design patent) provided a written description of the claimed genus of protein conjugates (i.e., utility patent), but instead, whether the disclosure of one species in the '894 patent is sufficient to described the entire genus as presently claimed. As discussed supra, the '894 patent does not reasonably convey to those skilled in the art that applicants at the time of the invention were in possession of the claimed genus of protein conjugates.

#### **Rejections Maintained:**

Claims 1-9, 11-21, 23-29 and 31-41 **remain** rejected under 35 U.S.C. 102 (b) and 103 for the reasons of record in the prior office action.

Applicants maintain that the rejections are improper because the claims are afforded the priority date of the '894 patent. In response to this argument, the claims are not granted this date and as such the rejection stands.

Claims 1-9, 11-21, 23-29 and 31-41 **remain** provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-47 of copending Application No. 10/438,219.

Applicants assert that because the rejection is provisional, applicants will not address this rejection in the forthcoming Appeal.

Therefore, NO claim is allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**  
9/26/05